

# **WEINER Declaration**

- 2 - (08/08/11) (XLS)

## **DECLARATION OF BARRY WEINER IN SUPPORT OF PETITION FOR RECONSIDERATION OF ORDER TO SHOW CAUSE**

Sir:

Declarant provides the following Declaration in response to the "Order to Show Cause Why Decisions Reviving Applications Should Not Be Vacated," issued in July of 2008.

I, Barry Weiner, declare and say that:

***My Background***

1. I am a citizen of the United States residing in New York City.
2. Enzo is a New York corporation with a principal place of business at 60 Executive Blvd., Farmingdale, New York 11735, and has one of its corporate offices at 527 Madison Avenue, New York, New York 10022.
3. I am a co-founder, President and Chief Financial Officer of Enzo Biochem, Inc. ("Enzo").
4. I have held various management positions in Enzo since 1979.
5. I have a thorough knowledge of Enzo's financial status since 1979.
6. The United States Patent and Trademark Office (USPTO) issued in July of 2008 an "Order to Show Cause Why Decisions Reviving Applications Should Not Be Vacated" which was expunged in June 2009 in favor of another "Order to Show Cause Why Decisions Reviving Applications Should Not Be Vacated" (Order).
7. The Order requests an explanation for the alleged delay in filing various petitions to revive and a showing that any delays in filing such petitions were unintentional.

***Overview of the Declaration***

8. I will first provide some background on Enzo followed by a discussion of the financial difficulties the company endured for the better part of a decade beginning in the late 1980s.
9. I will then comment on the company's response to its financial difficulties and how it functioned with limited resources during this period of financial crisis. I will

explain the circumstances as to why Enzo was unable to increase the number of legal staff employed (particularly attorneys) until around 2003, how Enzo was financially victimized by events which occurred in the early 1990s, and how these events led to a cautious mindset in the management of Enzo. In fact, during these years Enzo had to manage with minimal executive and management staff, including its in-house legal staff.

10. Finally, I will comment on Mr. Ronald Fedus who is presently the Corporation and Patent Counsel for Enzo. I will discuss Mr. Fedus' duties and his workload as primary (and at times sole) legal counsel for Enzo with respect to patent and other legal matters from February 1990 to the present. I know Mr. Fedus as a hard-working employee who actively attended to his duties.

#### *Background of Enzo*

11. Enzo was founded in 1976. Since then, Enzo has concentrated on the development of enabling technologies in the areas of gene regulation, gene modification, and nucleic acid detection. Enzo's technologies are applicable to the biomedical and pharmaceutical research markets. For example, one such technology led to the development of today's most widely utilized molecular diagnostic assay—the Human Papillomavirus test (HPV). This test is the standard of care for women undergoing gynecological examinations and is thought to be a key factor in the decline in incidence of cervical cancer. Enzo's discoveries are also used in the identification of various genetic disorders as well as in the process of drug discovery.

12. The business activities of Enzo Biochem are performed by Enzo's three wholly owned subsidiaries: Enzo Life Sciences, Enzo Therapeutics and Enzo Clinical Labs.

13. These activities include research and development, manufacturing and marketing of biomedical research products and tools through Enzo Life Sciences, the research and development of therapeutic products through Enzo Therapeutics, and the operation of a regional clinical reference laboratory through Enzo Clinical Labs.

***Onset of Financial Difficulties***

**14.** Enzo's financial difficulties began in the late 1980s and extended up to about 1996. These financial difficulties were largely the outgrowth of a disputed collaborative matter between Enzo and a large corporate partner. The partner suspended payments required by its collaboration agreement with Enzo resulting in protracted litigation from 1987 to about 1993.

**15.** In further detail, Enzo entered into a collaboration agreement with this large corporate partner in the early 1980s. The subsidiary of this corporate partner entered into an agreement to pay Enzo a significant sum over a four and one-half year period in support of research and development projects which could be extended into the future. After paying less than half the amount owed, the subsidiary reneged. The resulting loss of revenues - including the later costs of litigation - further harmed Enzo's financial status. The ongoing dispute with the subsidiary caused Enzo enormous harm in the marketplace, because Enzo was unable to pursue business opportunities with other partners while the matter was pending in court. In the early and mid 1990s, outside legal counsel was hired for litigation matters (but not for patent prosecution matters). Enzo paid outside legal counsel on a contingency basis or by payment with company stock.

**16.** Enzo's dealings with this corporate partner impacted Enzo's financial condition with respect to other matters as well. The dispute impacted separate financial obligations related to bonds, a lease and the attempted renovation of a real estate property, all of which resulted in a further deterioration in Enzo's financial state.

**17.** Bond obligations went into default because of the corporate partner's suspension of payments. Enzo's survival required the company to undergo a radical restructuring and downsizing. In 1992, Enzo was even involved in discussions for a "prepackaged bankruptcy," which is a financial reorganization plan made in cooperation with a company's creditors in preparation for bankruptcy.

**18.** Additionally, costly and time-consuming renegotiations with numerous individual bond-holders were necessary.

**19.** Because the early 1990s were a critical time-period in biotechnology for growth, Enzo lost a crucial foot-hold in the market. In sum, Enzo only survived this

difficult period by negotiating with debt holders and undertaking radical cost-saving steps throughout the company and its operations.

***Responding to Financial Difficulties Required Stern Measures***

20. In light of these financial difficulties, Enzo's very survival required stern measures affecting all operations of the company. These financial difficulties also limited Enzo's ability to provide additional resources to Mr. Fedus from the early 1990s to around 1996. Further, in view of these past difficulties, Enzo acted prudently post-1996, even as Enzo's financial state began to improve, by continuing a conservative approach to management of overhead and operations. This meant that executives and management, including Enzo's law department, undertook extensive workloads and responsibilities in order for the company to survive.

21. Enzo proceeded cautiously by utilizing existing personnel who had proven themselves to be reliable.

22. Even when financial conditions improved somewhat in 1996, Enzo continued its fiscal conservatism in its management and operations. Enzo did not significantly expand its personnel, particularly executive personnel including legal staff, out of concern that further financial difficulties might be encountered.

***Functioning with Limited Resources***

23. Enzo's poor financial condition in the early 1990s up to 1996 only allowed Enzo to operate on a "shoestring" budget. During one period from around 1990 to 1992, Enzo moved its corporate headquarters into a three room space in New York City which served as Enzo's temporary corporate offices. Mr. Fedus worked with two other Enzo employees from one room in this office space while the remaining executive functions of the company were run from the other two rooms.

24. Enzo has always been careful about budgeting its resources and therefore it has been Enzo's practice to not actively seek out expensive litigation. Nonetheless, during the early 1990s, Enzo was involved in a number of litigations (primarily breach of contract disputes relating to, for example, distributorship agreements). Most of these matters were instigated by the adverse party. Enzo generally paid outside legal counsel

on contingency or through the payment of company stock because of Enzo's financial condition.

25. Enzo personnel were relied upon to manage the operations of Enzo. Mr. Fedus was called upon to manage Enzo's intellectual property assets and legal concerns because of his track record of good performance. Enzo eventually began to expand the number of upper-level personnel, including legal personnel, around the mid-2000s but only after a thorough vetting process. It was not until 2003 that Enzo hired an additional patent attorney (Ms. Natalie Bogdanos) as a full-time employee. Presently, Mr. Fedus and Ms. Bogdanos are the only attorneys employed by Enzo.

26. From 1994 to around 2003, Enzo hired no additional executive personnel. Some executives and legal staff (Mr. Fedus) had to take on multiple responsibilities during this period of time. In sum, Enzo undertook a prudent financial approach to management of the business in order to survive.

27. These circumstances led to significant demands made not only on Enzo's law department, but on all of Enzo's management and operations. Thus, Enzo's desire to maintain a small network of proven employees resulted in Mr. Fedus having to undertake an extraordinary number of additional responsibilities.

28. Enzo has always placed a high value on its intellectual properties, viewing its patent estate as the company's most precious asset. Mr. Fedus was charged with the responsibility of protecting and enhancing this important corporate asset. As Mr. Fedus is a professional and experienced patent attorney, registered to practice before the USPTO, with solid law-firm patent prosecution experience behind him, I and my fellow corporate executives have always relied on him to fulfill his responsibilities, particularly in regards to Enzo's patent portfolio. While Mr. Fedus' assignments were numerous and varied, there was no reason for management to suspect that he could not effectively handle the various responsibilities entrusted to him. Mr. Fedus was given the authority to act with virtually complete autonomy as he prosecuted Enzo's patent applications. He outsourced prosecution work on an as needed basis and as Enzo's financial condition permitted. He and his support staff maintained a calendar and docket system. He independently reviewed and approved bills for services, including disbursements, from

outside counsel and experts he independently selected and engaged in connection with prosecuting and enforcing Enzo's patents and rights worldwide.

29. Based on the success of Mr. Fedus' efforts in maintaining and increasing Enzo's patent portfolio, I and my fellow executives had every reason to believe that Mr. Fedus continually performed an outstanding job in securing and protecting Enzo's worldwide patent portfolio.

30. I am also aware that Mr. Fedus has competently handled numerous other non-patent legal matters for Enzo.

31. In my opinion, Mr. Fedus attends to all legal matters in a professional and conscientious manner.

32. It is my belief that Mr. Fedus acted professionally in addressing each matter he handled, both patent related and non-patent related, in a thorough and timely manner.

33. As President of applicant Enzo, I categorically state that Enzo never intended to nor was Enzo motivated in any way to abandon its inventions or to intentionally delay filing responses in any of Enzo's pending patent applications beyond statutorily permitted deadlines.

34. Indeed, Enzo had every reason and need to actively and vigorously pursue its patent portfolio, which formed the very basis for the company's survival and growth and which underlie its products, technologies, distributorships, licensing efforts, enforcement litigations, commercial relationships, reputation, scientific collaborations with academia, and the like. In light of the financial circumstances Enzo had experienced, it would have been a total contradiction for Enzo *not* to pursue and obtain its patents as vigorously and as timely as possible.

35. Enzo only stood to gain from acquiring patents; there was absolutely no reason which would have benefitted Enzo in delaying their acquisition. Indeed, delaying the acquisition of patents could only hurt Enzo which had several extensive distributor relationships with life sciences companies. Upon issuance of patents to Enzo, more products were distributed and greater revenue was generated for the company. Thus, the issuance of patents was crucial to Enzo's survival and financial well-being.

36. Further, products protected by patents provided a revenue stream for a substantial period of time clear of competitor's infringing goods, and at the same time patent-protected products protected the public from acquiring possibly inferior goods. Securing patents also allowed Enzo to cultivate other new and valuable business relationships for distributing Enzo products to the marketplace.

***Mr. Ronald Fedus***

37. In 1991, Enzo's legal staff consisted of Mr. Ronald Fedus, Mr. Serle Mosoff, Ms. Elaine Brenner, and Ms. Hilary Smith (who was not a patent attorney).

38. By 1992, Enzo's legal staff was reduced to Mr. Fedus and Ms. Brenner and finally, from 1993 until about 2003, Mr. Fedus was Enzo's sole in-house patent lawyer with the exception of one other attorney who was briefly employed for about a one year period around 2001.

39. When Mr. Fedus joined Enzo in early 1990, he inherited a U.S. prosecution docket of almost 50 families of patent applications and their foreign counterparts. He was also given responsibility for dealing with non-patent matters involving the Company.

40. Mr. Fedus' workload increased as Enzo's legal staff dwindled. As I explained earlier, Enzo, like most developing companies, desired to expand and grow but a series of financial difficulties, primarily in the early 1990s, prevented this expansion and growth from occurring.

41. Mr. Fedus' duties as Corporation and Patent Counsel are broad and far-ranging. Mr. Fedus has, for example, primary responsibility for Enzo's patent and trademark matters including U.S. and foreign patent and trademark prosecution, opposition and interference proceedings, and litigation involving Enzo's intellectual property rights. In addition, Mr. Fedus handled non-intellectual property matters including real estate transactions, licensing matters and contracts.

42. The United States Patent and Trademark Office (USPTO) has issued a number of "Show Cause Orders" affecting several Enzo patents and patent applications. These Orders question whether Mr. Fedus' failure to file timely replies to certain U.S. prosecution matters may have been intentional.

43. I personally know that Mr. Fedus has successfully prosecuted numerous patent applications into patents.

44. I also personally know that he has competently and timely handled numerous other, non-patent legal matters.

45. In my opinion, Mr. Fedus attends to all legal matters in a professional and conscientious manner.

46. It is my belief that Mr. Fedus addressed all patent prosecution matters in the proper manner by giving each matter its necessary and thorough review and analysis.

47. It is my understanding that, in prosecuting U.S. patent applications, Mr. Fedus received Office Actions from the USPTO, and prepared responses and claim amendments in these applications. He did this by reviewing the file histories of the relevant cases, any cited prior art, and interviewing inventors and other technical experts. I specifically recall many instances where Mr. Fedus interviewed inventors and technical experts.

48. Each action required Mr. Fedus to perform a number of acts to ensure that the matters were well handled because patents are critical assets for Enzo. It has been Enzo's ongoing business plan to develop and market new and innovative technologies; therefore, Enzo has always placed a high value on ensuring the proper procurement and maintenance of patent protection.

49. It is my opinion that Mr. Fedus acted professionally in addressing each matter in a thorough manner which required extensive analyses and review from scientific, technical and legal standpoints, especially in view of the amount of work he was handling with limited resources.

50. It is because Mr. Fedus actively and thoroughly attended to all matters, that certain responses may have been unintentionally delayed.

51. I certainly do not believe that any delay was an intentional action by Mr. Fedus to forestall prosecution. My basis for such belief includes Mr. Fedus' record for timely prosecuting other matters, his general reputation, my personal experience with Mr. Fedus, and the fact that Enzo needed to obtain patents for inventions considered to be substantial assets of the company. In fact, Mr. Fedus was intimately involved in a number of distribution agreements with other life sciences companies for Enzo products

which were protected by U.S. and foreign patents. Typically in those distribution agreements, more products were distributed and higher revenues were generated for Enzo upon issuance of its patents and without the need for further negotiations.

**52.** Thus, it would have been altogether contrary to Enzo's interests to delay the issuance of any patent because Enzo's patent portfolio was vital to the company's financial well-being, as well as its future growth and survival.

I declare that all statements made herein are based on personal knowledge or upon information and belief and are believed to be true; and further that the statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Respectfully submitted,



Barry Weiner, President & CFO  
Enzo Biochem, Inc.

8/31/09

Date